

Evaluation of Strategies to Achieve Cost Savings for Medicaid Prescription Drugs

As Required by

2020-21 General Appropriations

Act, House Bill 1, 86th Legislature,

Regular Session, 2019 (Article II,

HHSC, Rider 30)

Health and Human Services

Commission

September 2020

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Executive Summary

The 2020-21 General Appropriations Act, House Bill 1, 86th Legislature, Regular Session, 2019 (Article II, Health and Human Services Commission [HHSC], Rider 30), requires HHSC to evaluate strategies to achieve cost savings for Medicaid prescription drugs, including the direct dispensing of prescription drugs by physicians, and to submit a report with findings and recommendations for achieving cost savings to the Governor, the Legislative Budget Board, and the appropriate standing committees of the legislature. This report is due by September 1, 2020.

HHSC requested that pharmacy stakeholders and managed care organizations (MCOs) submit potential cost saving strategies to HHSC. Five potential strategies are included in this report. For each strategy, HHSC conducted research and performed analyses of relevant data, as available. Three of these strategies had insufficient data available to determine potential cost savings, while two may have potential savings as summarized below:

- Physician Dispensing This approach involves physicians providing medication directly to the patient. Research to determine cost effectiveness for Texas Medicaid was inconclusive due to lack of access to necessary data.
- Closed Formulary This approach is used by commercial health plans to obtain better rebates with manufacturers. Research on the use of a closed formulary was inconclusive due to lack of data. No other state Medicaid program was identified as having implemented this model.
- Tiered Formularies This approach includes tiers of preferred and nonpreferred medications with varying copayments. Potential cost savings for this model are unpredictable because of federal limitations on cost sharing in Medicaid and services cannot be withheld for failure to pay which may result in inconsistent collection of copayments.
- Transition of Care Transition of care (TOC) is part of medication therapy
 management (MTM) using pharmacists' expertise to reconcile medications for
 individuals discharged from inpatient hospital admissions. Medication-related
 issues such as insufficient awareness of how to properly take medications
 and adverse drug events due to insufficient medication reconciliation can
 contribute to hospital readmissions. While it is not possible to predict specific
 outcomes, research suggests TOC interventions may result in decreases in
 overall Medicaid utilization and expenditures.

HHSC requires MCOs to provide discharge planning for members transitioning out of an inpatient setting or a nursing facility to ensure the member is

assessed and there is a plan to address the member's needs at discharge. This transition plan may include TOC medication therapy management. HHSC could work with MCOs and other stakeholders to assess TOC interventions that are occurring today and if integrating pharmacist TOC provides opportunities for improvements.

 Over-the-Counter Drugs as Value-Added Services (VAS) - A value added service (VAS) is an additional service MCOs may provide to their members at no additional cost to HHSC. This strategy may lead to fewer medical appointments by members seeking a prescription for medications. However, the savings potential would depend on the number of MCOs electing to participate in such a program.

HHSC will continue to consult with stakeholders and other states to research additional strategies and innovative methods to achieve cost savings for prescription drugs. Additionally, HHSC will continue to monitor federal law to assess any changes in the regulations, which may lead to other cost savings opportunities.

1. Introduction

Pursuant to the 2020-21 General Appropriations Act, House Bill 1, 86th Legislature, Regular Session, 2019 (Article II, HHSC, Rider 30), HHSC evaluated the direct dispensing of prescription drugs by physicians as a potential cost saving strategy. In addition, HHSC conducted outreach to pharmacy stakeholders and MCOs requesting that they submit supplementary strategies for research and analysis. The agency received responses from stakeholder groups including MCOs, pharmacy benefit managers, professional associations, and pharmacies that encompassed strategies such as a closed formulary demonstration, a tiered formulary and cost sharing, transition of care medication therapy management, and over-the-counter drugs as a value-added service. HHSC reviewed each strategy for the potential to provide cost-savings and conducted research and performed analyses of relevant data, as available. The following report explores each identified strategy and subsequent findings.

2. Potential Cost Savings Strategies

HHSC completed an evaluation of physician dispensing as directed by Rider 30 and other cost-saving strategies recommended by stakeholders. The following sections provide an overview of each strategy, information on relevant federal rules or regulations, and the potential for cost savings.

Physician Dispensing

Physician dispensing is defined as providing medication directly to the patient during the healthcare visit. In Texas, physicians may only dispense drugs under the following limited circumstances:

- 1. In an emergency situation.
- 2. Free samples provided by a drug manufacturer, if the physician determines dispensing the samples is advantageous to the patient.
- 3. "Dangerous drugs"² to patients in certain rural areas under certain conditions.

Texas physicians looking to expand the circumstances to dispense medication filed a lawsuit on June 27, 2019, in the Travis County District Court against the Texas State Board of Pharmacy and the Texas Medical Board to overturn a ban on doctor dispensing of biologics and prescription drugs to patients.³

Within the last year, stakeholders have provided varied feedback on the cost effectiveness of physician dispensing of medications. Some stakeholders indicated physician dispensing is cost effective because the convenience for members leads to improved medication adherence and outcomes. Others indicated it increases costs because reimbursement for medical services is often based on Average Wholesale Price which is higher than standard pharmacy pricing of National Average Drug Acquisition Cost.

States use different reimbursement methodologies for physician dispensing of drugs. HHSC examined the Medicaid programs of two large states: Florida and New York. These states manage reimbursement differently.

Florida's Medicaid program uses a single reimbursement methodology for prescription drugs for both pharmacies and providers enrolled as dispensing practitioners. This payment methodology applies to claims submitted by a pharmacy as a pharmacy claim or by physicians as a medical claim. Both pharmacies and physicians are paid the same dispensing rate. Alternatively, the New York Medicaid program treats physician dispensed drugs as a medical benefit.⁴

¹ Defined in Texas Occupations Code § 158 (https://statutes.capitol.texas.gov/Docs/OC/htm/OC.158.htm).

² Defined in Texas Health and Safety Code § 483.001(2) (https://statutes.capitol.texas.gov/Docs/HS/htm/HS.483.htm).

https://ij.org/wp-content/uploads/2019/06/Original-Petition-FILE.pdf

⁴ https://health.ny.gov/health_care/medicaid/program/update/2020/no12_2020-07.htm#prescriber

Reimbursement for drugs provided by physicians to their patients is based on the acquisition cost to the physician of the drug dose administered to the patient. For these drugs, it is expected the practitioner will maintain auditable records of the actual itemized invoice cost of the drug, including the numbers of doses of the drug represented on the invoice.⁵

Conclusion

In Texas, Medicaid providers are not contractually required to provide HHSC information on the cost of physician dispensing. Because of this, HHSC does not have sufficient information to determine a proposed reimbursement rate for comparison to the pharmacy benefit and is consequently unable to assess cost effectiveness of this strategy for Medicaid. If a physician dispensing fee were established in Texas Medicaid, it would apply to fee-for-service Medicaid and MCOs would be allowed to negotiate and set dispensing fees.

Closed Formulary Demonstration

A closed formulary allows commercial health plans to limit the number of drugs on their formulary and thereby negotiate greater rebates with manufacturers seeking inclusion on their limited formulary. A closed formulary limits the number of commercially available drugs in each therapeutic class, whereas an open formulary includes all such drugs in each therapeutic class. In addition to commercial plans, Medicare Part D plans also use closed formularies with at least two drugs per therapeutic class, as authorized under 42 Code of Federal Regulations (CFR) 423.120. Medicare Part D plans may also implement a closed formulary with one drug per class if only one drug is available, or, if only two drugs are available, but one drug is clinically superior.

Section 1927 of the Social Security Act, relating to payment for covered outpatient drugs, requires states providing Medicaid outpatient prescription benefits to cover all drugs produced by manufacturers participating in the Medicaid Drug Rebate Program. This is referred to as an open formulary, the type currently maintained by HHSC. However, states can explore a closed formulary demonstration either through the 1115 Waiver application or the Healthy Adult Opportunity (HAO) program.

The Department of Health and Human Services will only consider an 1115 Waiver application for a closed formulary if all parts of Section 1927 are waived. This means the state would no longer operate under the optional outpatient drug program and would develop a new program under an 1115 demonstration. Furthermore, it requires the state to negotiate directly with manufacturers and give up all federal rebates available under the Medicaid Drug Rebate Program.

In the past, other states' 1115 waiver applications were denied by the Centers for Medicare and Medicaid Services (CMS) or are still under review. In 2018, CMS

 $^{^{5}\} https://www.emedny.org/Provider Manuals/Physician/PDFS/Physician_Procedure_Codes_Sect 2.pdf$

denied the Massachusetts proposal because it preserved rebates through the federal Medicaid Drug Rebate Program. CMS noted it would reconsider the proposal if the state agreed to forgo these mandatory rebates. In 2019, Tennessee proposed an amendment to allow flexibility under their demonstration to adopt a commercial-style closed formulary with at least one drug available per therapeutic class. Tennessee also requested flexibility to exclude new drugs approved through the Food and Drug Administration's accelerated approval process that have not yet demonstrated actual clinical benefit. These drugs would be excluded from its formulary until market prices are consistent with prudent fiscal administration, or the state determines that sufficient data exists regarding the cost-effectiveness of the drug. At the time of this report, CMS has not approved Tennessee's proposed changes.

Through the HAO, CMS allows states to adopt a closed formulary without reducing manufacturer rebate obligations. However, this initiative only applies to adults under age 65 who are not eligible for Medicaid on the basis of disability or need for long term services and supports, and who are not currently eligible under the state plan.⁸ Thus, the HAO option would not provide savings.

Conclusion

The ability to achieve cost savings under a closed formulary model is dependent on the structure of the 1115 demonstration and CMS approval. As no other state has been allowed to implement either change, HHSC was unable to estimate potential cost savings.

Tiered Formularies and Cost Sharing

Commercial health plans and Medicare use a formulary model based on drug tiers. A tiered formulary divides drugs into groups based mostly on cost. Under this model, a formulary might have three, four, or even five tiers and all covered drugs have a preferred or non-preferred status. Drugs listed as preferred are available without prior authorization and have lower copayments. Drugs identified as non-preferred require prior authorization and have higher copayments. Some states apply different copayment amounts for brand and generic prescription drugs. The copayments are associated with prescriptions with a higher purchasing cost for the health plans and help offset the increased costs to the health plans for these drugs.

Using a tiered formulary or requiring copayments for Medicaid would require CMS approval. Federal policy has limitations on copayments and cost sharing as follows, which would restrict collections particularly in Texas Medicaid.

 Federal law caps copayment amounts to four dollars for preferred drugs and eight dollars for non-preferred drugs for individuals with incomes at or below

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⁶ https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-ca.pdf

⁷ https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/tn-tenncare-ii-pa10.pdf

⁸ https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf

150 percent of the federal poverty level (FPL). The maximum drug copayments for individuals with incomes above 150 percent of the FPL is four dollars for preferred drugs and up to 20 percent of the cost the agency pays for non-preferred drugs.⁹

- Copayments are a component of cost sharing, which has additional federal limits. Cost sharing, including copayments, cannot exceed 5 percent of family income.
- There are also mandatory exempt populations (e.g., children 18 and under (with some exceptions); pregnant women under 150 percent of FPL; certain individuals in institutions; women enrolled in the Breast and Cervical Cancer Treatment Program).
- Certain drug classes like family planning and tobacco cessation are exempt from cost sharing requirements.

As of January 1, 2020, 18 state Medicaid programs have copayments for their adult expansion populations for generic drugs and 21 states require copayments for preferred and non-preferred brand name drugs. ¹⁰ Currently, Texas Medicaid does not require prescription drug copayments for Medicaid recipients.

Conclusion

The impact of collecting copayments in Texas Medicaid is restricted due to federal limitations described above and because services cannot be withheld for failure to pay, which may result in the inconsistent collection of copayments.¹¹

Transition of Care Medication Therapy Management

TOC is a part of MTM using pharmacists' expertise to reconcile medications for individuals discharged from inpatient hospital admissions. Medication-related issues such as insufficient awareness of how to properly take medications and adverse drug events due to inadequate medication reconciliation can contribute to hospital readmissions.

HHSC requires MCOs to provide discharge planning for members transitioning out of an inpatient setting or a nursing facility to ensure the member is assessed and the MCO, the member, their providers, and their family or other supports have a plan to address the member's needs at discharge. This transition plan may include TOC medication therapy management.

The goal of a medication TOC program is to safely transition patients from hospital to home by coordinating care with physicians and educating patients. Community pharmacies can play a role in TOC by performing tasks such as bedside delivery at discharge, 72-hour post-discharge telephone calls, comprehensive medication reconciliation, and educating members on how to properly take medications and on

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⁹ https://www.medicaid.gov/medicaid/cost-sharing/cost-sharing-out-pocket-costs/index.html

¹⁰ https://www.kff.org/health-reform/state-indicator/premium-and-cost-sharing-requirements-for-selected-services-for-medicaid-expansion-adults/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

¹¹ https://www.medicaid.gov/medicaid/cost-sharing/cost-sharing-out-pocket-costs/index.html

drug interactions. In a TOC model, the pharmacist develops a medication management plan for the individual. Pharmacies can bill for these services using the National Council for Prescription Drug Programs (NCPDP) Standard, which is the required submission format for pharmacy claims. Using NCPDP ensures consistent implementation of TOC using fields, values, and code sets developed by the pharmacy industry.

In collaboration with MCOs and other pharmacy stakeholders, HHSC could examine the effects of TOC on utilization and expenditures for chronic diseases such as diabetes and asthma. In state fiscal year (SFY) 2019, diabetes accounted for approximately \$429,134,166, and asthma accounted for \$102,961,450 in total acute care medical Medicaid expenditures.¹²

Conclusion

Individuals experiencing changes in care settings (e.g., going from a hospital to home), changes in medications (types, schedule, dosing), and those prescribed multiple medications by different prescribers are at greater risk for serious adverse drug events, emergency department visits, and hospital readmissions. Studies show evidence and potential for decreased hospital readmissions among patients who received TOC interventions, especially those in chronic disease states. HHSC to predict specific outcomes, research suggests TOC interventions may result in future decreases in overall Medicaid utilization and expenditures, with better adherence leading to better health outcomes. HHSC could work with MCOs and other stakeholders to assess TOC interventions that are occurring today and if integrating pharmacist TOC provides opportunities for improvements.

Over-the-Counter Drugs as a Value-Added Service

A VAS is an additional service MCOs may provide to their members at no additional cost to HHSC. A VAS may be actual health care services, benefits, or positive incentives that HHSC determines will promote healthy lifestyles and improved health outcomes among members. Currently, MCOs cannot offer over-the-counter (OTC) drugs as a VAS since many are covered on the formulary and already available to members by prescription.

 $^{^{12}}$ The managed care data component in these figures may include some Long-Term Services and Supports waiver services.

¹³ Budlong, H; Brummel, A; Rhodes, A; Nici, H. Impact of Comprehensive Medication Management on Hospital Readmission Rates. Population Health Management, 2018, Sep:26 (5) Retrieved October 25, 2018, from https://doi.org/10.1089/pop.2017.0167.

¹⁴ Ni, W., et al. (2018). Budget Impact Analysis of a Pharmacist-Provided Transition of Care Program. Journal of Managed Care & Specialty Pharmacy, Vol. 24, No. 2.

¹⁵ Heaton, P. C., et al. (2019). Improving care transitions through medication therapy management: A community partnership to reduce readmissions in multiple health-systems. Journal of the American Pharmacists Association 59 (2019), 319-328. Retrieved May 20, 2020, from https://doi.org/10.1016/j.japh.2019.01.005.

¹⁶ Jones, C. D., et al. (2018). The effect of a pharmacist-led multidisciplinary transitions-of-care pilot for patients at high risk of readmission. Journal of the American Pharmacists Association, 58 (2018) 554-560. Retrieved May 20, 2020, from https://doi.org/10.1016/j.japh.2018.05.008.

HHSC could work with CMS to explore greater flexibility to allow MCOs the opportunity to offer their members OTCs as a VAS. This may reduce prescription drug costs for certain drugs such as antihistamines for allergies. In SFY 2019, Medicaid reimbursed pharmacy providers approximately \$5,545,970 on OTC antihistamines.

Conclusion

This strategy may lead to fewer medical appointments by members seeking a prescription for medications that otherwise require none. Decreasing appointments and prescriptions may generate savings overall in the Medicaid program. A few MCOs have expressed interest in offering OTCs as a value-added benefit. However, savings potential would depend on the number of MCOs electing to participate in such a program and may be minimal because HHSC can't mandate a value-added service. The more MCOs who participate will lead to better opportunities for cost savings.

3. Conclusion

HHSC completed an evaluation of five potential cost-saving strategies proposed by the Texas Legislature and partnering stakeholder groups. Limited available data sources precluded the agency's ability to determine any potential cost savings for three of the five reviewed strategies. These strategies included physician dispensing, use of a closed formulary, and use of a tiered formulary and cost sharing. However, HHSC's evaluation of the remaining two strategies, transition of care medication therapy management and over-the-counter drugs as a value-added service, yielded a potential for cost savings.

HHSC will continue to consult with stakeholders and other states to research additional strategies and innovative methods to achieve cost savings for prescription drugs. Additionally, HHSC will continue to monitor federal law to assess any changes in the regulations, which may lead to other cost savings opportunities.

List of Acronyms

Acronym	Full Name
CMS	Centers for Medicare and Medicaid Services
FFS	Fee-For-Service
FPL	Federal Poverty Limit
HAO	Healthy Adult Opportunity
HHSC	Health and Human Services Commission
MCO	Managed Care Organization
MTM	Medication Therapy Management
NCPDP	National Council for Prescription Drug Programs
ОТС	Over-The-Counter
SFY	State Fiscal Year
TOC	Transition of Care
VAS	Value-Added Service